

EPA Registration Number 74468-13

PROCESSING REQUEST

Reg #: 74468-13

Decision #: 497616

Description: new product

Material Available Electronically (see PPLS):

☐ Electronic Label/Letter Dated: 12/8/14

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated: 12/8/14

☐ Notification Dated:

☐ New CSF(s) Dated: 11/20/14

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Erik Kraft

Division: RD

Phone: 308-9358

Date: 12/15/14



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

74468-13

Date of Issuance:

12/8/14

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Metsulfuron-methyl Technical

Name and Address of Registrant (include ZIP Code):

ProActive, LLC
P.O. Box 5068
Brookfield, CT 06804

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Shaja Joyner, Product Manager 20
Fungicide and Herbicide Branch, Registration Division (7505P)

Date:

12/8/14

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Metsulfuron-methyl GDCI-122010-1306 / under docket ID EPA-HQ-OPP-2011-0375 at www.regulations.gov.

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 74468-13."
4. Submit one copy of the final printed label for the record before you release the product for shipment.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/20/14

If you have any questions, please contact Erik Kraft at (703) 308-9358 or kraft.erik@epa.gov.

Shaja Joyner, Product Manager 20
Fungicide and Herbicide Branch
Registration Division (7505P)

Attachment

Metsulfuron-methyl Technical

For Formulation Use Only

INGREDIENT STATEMENT

	By Weight
ACTIVE INGREDIENT: Metsulfuron-methyl*	98.0%
OTHER INGREDIENTS:	2.0%
TOTAL	100.0%

* methyl 2-[[[4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]-carbonyl]sulfonyl]benzoate

ACCEPTED

12/08/2014

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No.

74468-13

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID (Sulfonylurea)	
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN Recommendations for Medical treatment for Metsulfuron-methyl Acute Toxicity: No specific antidote. Treat symptomatically.	
HOTLINE NUMBER (Sulfonylurea) Have the product container or label with you when calling a poison control center or doctor, or going for treatment. for information on this product, contact the national Pesticide Information Center, 1-800-858- 7378, Monday-Friday, 7:30 AM-3:30 PM PST. You may also contact the National Poison control Center, 1-800-222-1222, day or night, for emergency medical treatment information.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS ON LABEL

NET WEIGHT: 25 Kgs. (55.1 Lbs.)

Manufactured for:
ProActive, LLC
P.O. Box 5068
Brookfield, CT 06804

EPA Reg. No. 74468-(to be assigned)
EPA Est. No. 69821-CHN-5

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals. Avoid contact with skin and clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this pesticide into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

INSTRUCTIONS TO FORMULATORS:

This technical product may be used for the manufacture of herbicide products for the following uses:

Terrestrial Food Crops

Wheat (including Durum), Barley, Pasture, Rangeland and Fallow Land.

Terrestrial Non-Food

Non-crop industrial sites, such as, airports, military installations, fence rows, roadside and associated rights-of-way, petroleum tank farms, pipeline and utility rights-of-way, pumping stations, railroads, storage areas, plant sites, governmental and private lands.

Turf, Industrial (unimproved only)

Rangelands and Pastures

Formulators using the product are responsible for obtaining EPA registration for their formulated products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store Metsulfuron-methyl Technical in a cool, dry place away from food, drink and animal feedstuffs. If spilled, do not flush to waterways (see Environmental Hazards). Carefully connect and containerize spilled material in a manner that produces the least amount of airborne dust. Suitable protective equipment should be worn during any spill cleanup operation (see precautionary Statements).

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or pressure rinse) promptly after emptying. Then offer for recycling or reconditioning if available, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Plastic or Metal containers: Triple rinse as follows: Empty the remaining contents into formulation equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into formulation equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Once container is rinsed, offer for recycling if available, or puncture and dispose of in a sanitary landfill.

EMERGENCY RESPONSE

For 24-hour emergency information regarding spills, leaks, exposure, or accidents, call, CHEMTREC 1-800-424-9300.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

ProActive, LLC warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use. This warranty does not extend to the use of the product contrary to proper instructions, or under abnormal conditions or other conditions not reasonably foreseeable to or beyond the control of Seller or ProActive, LLC and Buyer and user assumes the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, PROACTIVE, LLC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR NEITHER A PARTICULAR PURPOSE NOR ANY OTHER EXPENSE OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law ProActive, LLC or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF PROACTIVE, LLC AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF PROACTIVE, LLC OR SELLER, THE REPLACEMENT OF THE PRODUCT.

ProActive, LLC and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sales and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of ProActive, LLC.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 74468-RG/Metsulfuron-methyl Technical
DP Barcode: 424345
PC Code: 122010

From: Marianne Lewis, Biologist
Insecticides/Rodenticides Branch
Registration Division (7505P)

To: PM 24
Fungicide Herbicide Branch
Registration Division (7505P)

Applicant: ProActive LLC
c/o Biologic, Inc.
115 Obtuse Hill Road
Brookfield, CT 06804

Marianne Lewis
SCR
12/5/14

FORMULATION FROM EPA Reg. No. 74468-RG LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Metsulfuron-methyl:	98.0%
<u>Inert Ingredient(s):</u>	2.0%
Total	100.0%

BACKGROUND: The subject product, EPA Reg. No. 74468-RG, is a 100% repack of [REDACTED]. Therefore the following Toxicity Categories from the label of [REDACTED] will be assigned to the subject product: acute oral (81-1) – III; acute dermal (81-2) – III; acute inhalation (81-3) – IV; primary eye irritation (81-4) – IV; primary dermal irritation (81-5) – IV. The subject product will be classified as a skin sensitizer (81-6).

RECOMMENDATIONS:

- The subject product will be assigned the acute toxicity categories as listed above.
- The subject product will be classified as a skin sensitizer.

The acute toxicity profile for EPA Reg. No. 74468-RG is currently:

Acute Oral	III-IV
Acute Dermal	III
Acute Inhalation	IV
Primary Eye	IV
Primary Dermal	IV
Skin sensitization	skin sensitizer

NOTE: The acute toxicity requirements have been satisfied for the subject product.

328/10

LABELING:

ID #: 074468-RG METSULFURON-METHYL TECHNICAL

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wear long sleeved shirt, long pants, socks, shoes and chemical resistant gloves (such as or made out of any waterproof material, selection category A). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

FIRST AID:

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 12-12-14

Document Part Of: 74468-RG
MRID, If Any: _____

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

STEPHEN SCHAIBLE

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 11-21-14

Experts In-Processing Signature: B.B. Date 11-26-14 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>74468-RC</u>		EPA Receipt Date: <u>11-21-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<i>No inerts to review 100% Re-Pack</i>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					X
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with <u>PR Notice 86-5</u>					X
8	<u>Notice of Filing</u> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* Documentation: PASS / FAIL

Required forms are complete

* Inserts: PASS / FAIL

No inserts to review. 100% Re-Pack

* PRN 11-3: PASS / FAIL

No studies submitted

* Overall status: PASS / FAIL

JL

11-26-14

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 25, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-497616
EPA File Symbol or Registration Number: 74468-RG
Product Name: METSULFURON-METHYL TECHNICAL
EPA Receipt Date: 21-Nov-2014
EPA Company Number: 74468
Company Name: PROACTIVE LLC

JANE M. MILLER
BIOLOGIC, INC.
PROACTIVE LLC
115 OBTUSE HILL ROAD
BROOKFIELD, CT 06804-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "J. Miller", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

MP
{960752*~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 25

Receipt No.

S- 960752

EPA File Symbol/Reg. No.

74468-RG

Pin-Punch Date:

11/21/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300

Amount Due: \$ 1506.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Jennifer Haines

Date: 11/25/14

Remarks:

* Similarity Clinic *

Receipt for Section 3

S: 960752

Milestone Email:

Regulatory Type: Product Registration - Section 3



Resubmission: ☐ Yes ☒ No

Application Type: New Registration



Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No



Print Letter

Enter More Information

Tracking

Company: 74468 PROACTIVE LLC

Risk Manager: Registration Division, Risk Management Team 25



Product #: 74468-RG

Product Name: METSULFURON-METHYL TECHNICAL

Override#:

Me Too
Section3:

Me Too Product
Name:

Application Date: 20-Nov-2014



OPP Rec'd Date: 21-Nov-2014



Front End Date: 21-Nov-2014



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NEW REGISTRATION

Receipt Content

De

CSF

Paper Label

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 74468-XX	2. EPA Product Manager M. Ondish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Metsulfuron-methyl Technical	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) ProActive LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. XXXXXXXXXX Product Name XXXXXXXXXX	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products. This product is further defined under EPA No. 300; CR No. 44. This product is a "Re-Pack". The PRIA fee for this application is \$1,506.

Jane Miller Tel: (203) 740-1200; Fax: (203) 740-1220; Email: jmillers@biologicconsulting.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55.1 lbs.		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) 203-740-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Jane M. Miller	5. Date November 20, 2014		

Jane Miller

From: pay.gov.clev@clev.frb.org
Sent: Thursday, November 20, 2014 2:22 PM
To: jmill@biologicconsulting.com
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or by email at yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25IHJ5ND
Agency Tracking ID: 74710630779
Transaction Type: Sale
Transaction Date: 11/20/2014 02:22:20 PM EST

Account Holder Name: Lawrence A. Miller

Transaction Amount: \$1,506.00
Billing Address: 115 Obtuse Hill Road
Billing Address 2:
City: Brookfield
State/Province: CT
Zip/Postal Code: 06804
Country: USA
Card Type: Visa
Card Number: *****0280

Registration Number:
Company Name: ProActive LLC
Company Number: 74468
Action Code: R300

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

BIOLOGIC CONSULTING, Inc.
agribusiness professionals

November 19, 2014

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

Attention: Mindy Ondish (PM #25)

RE: "Metsulfuron-methyl Technical", EPA Reg. No. 74468-XXX
Application for Pesticide Registration – Re-Pack

Dear Ms. Ondish:

On behalf of ProActive, LLC we are submitting this Application for Pesticide Registration for the above mentioned product. The subject product is a 100% "re-pack" of "[REDACTED]"

The following documents are enclosed to process this registration:

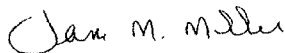
Volume 1 Administrative Materials

- Application for Pesticide Registration (EPA Form 8570-1)
- Formulator's Exemption Statement (EPA Form 8570-27)
- Confidential Statement of Formula (EPA Form 8570-4)
- Five (5) copies of draft labeling

This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products, EPA No. R300; CR No. 44. The PRIA fee for this application is \$1,506.

Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,



Jane M. Miller
Agent to ProActive, LLC



Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address ProActive, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	EPA File Symbol/Registration Number 74468-XX
	Product Name Metsulfuron-methyl Technical
	Date of Confidential Statement of Formula (EPA Form 8570-4) November 20, 2014

(1) This product contains the following active ingredient(s):

Metsulfuron-methyl

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

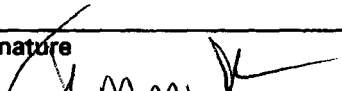
☒ (A) An accurate Confidential Statement of Formula (*EPA FORM 8570-4*) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Metsulfuron-methyl	<div data-bbox="566 1350 979 1386" style="background-color: black; height: 53px; width: 280px;"></div>	<div data-bbox="1060 1350 1219 1390" style="background-color: black; height: 60px; width: 107px;"></div> <div data-bbox="1518 1390 1533 1402" style="text-align: right;">+</div>
Signature 	Name and Title Jane M. Miller, Agent	Date 11/20/2014

*Product ingredient source information may be entitled to confidential treatment

Confidential Statement of Formula may be entitled to confidential treatment